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(54) Title: COMPOSITION FOR EXTENDING POST MEAL SATIETY

(57) Abstract: A nutritional composition in a dry powder form including an extract of potatoes that provides a source of proteinase inhibitor that is mixed with water and ingested before a meal which extends satiety and thereby reduces appetite. The nutritional composition includes between about 10 % and about 80 % by weight of a protein, between about 10 % and about 40 % by weight of a medium to long chain fatty acid, between about 2 % and about 5 % by weight of a calcium salt, and between about 1 % and about 5 % by weight of a proteinase inhibitor provided by the extract of potatoes.

COMPOSITION FOR EXTENDING POST MEAL SATIETY**BACKGROUND OF THE INVENTION****Field of Invention**

5 The present invention relates to a nutritional composition for extending satiety following a meal. More particularly the nutritional composition includes protein, medium and/or long chain fatty acids and calcium to stimulate the secretion of cholecystokinin a gastric peptide, and a source of proteinase inhibitor extracted from potatoes that prevents the breakdown of cholecystokinin. By increasing and sustaining the levels of cholecystokinin, the present
10 invention extends satiety.

Background of the Prior Art

 Over the last forty years there has been extensive research conducted on mechanisms that would extend satiety following the ingestion of a meal. The benefits of such an invention have obvious utility in producing weight loss. Weight loss research has focused on three areas.
15 Because the brain plays an essential role in the control of appetite, researchers have looked at various neurotransmitters, specifically, serotonin, dopamine and nor-epinephrine. A number of prescription and over-the-counter products have been developed which influence these neurotransmitters, thereby reducing appetite. Reducing appetite pharmacologically has a number of drawbacks, including a loss of effectiveness over a period of time. Drugs that affect
20 neurotransmitters also affect the central nervous systems and can cause jitteriness and anxiety. In addition, these agents can produce cardiovascular effects that may even be fatal.

 A second approach has focused on slowing gastric emptying thereby creating a feeling of fullness. This approach utilizes insoluble fibers, which slow the movement of food through the gastrointestinal tract. The disadvantage with the use of fiber is that the quantities needed to
25 produce an effect create an unpalatable diet as well as numerous gastrointestinal effects including bloating, gas and diarrhea.

The present invention provides for nutritional composition in a dry powder form for extending satiety following ingestion of a meal.

The dry nutritional composition includes proteins in the range of 10% to 80%. The protein can be in the form of soy, whey, casein or a specific amino acid mixture containing
5 essential amino acids or of the amino acid phenylalanine.

The dry nutritional composition also includes the mineral calcium in the range of 2% to 6%. The calcium can be in the form of a salt including calcium chloride, calcium carbonate, calcium lactate etc.

The dry nutritional composition also includes medium and/or long chain fatty acids (C₁₂-
10 C₂₂) in the range of 10%-40%.

The dry nutritional composition also includes a source of proteinase inhibitor extracted from potatoes wherein the protease inhibitor is present in the range of 0.02%-5%.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a graphical representation of the responses of test subjects as to their feeling of
15 satiety taken in fifteen minute intervals over a three and one-half hour period following a meal, showing both subjects who were administered a placebo and subjects who were administered a nutritional supplement according to the present invention.

Fig. 2 is a graphical representation of the responses of test subjects as to their feeling of
hunger taken in fifteen minute intervals over a three and one-half hour period following a meal,
20 showing both subjects who were administered a placebo and subjects who were administered a nutritional supplement according to the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The nutritional composition for nutritional intervention for extending satiety includes nutritional agents being protein, medium and/or chain fatty acids, calcium, an extract of potatoes
25 containing proteinase inhibitor, and, in a preferred form, flavoring agents and coloring agents. The proteinase inhibitor is a heat stable protein present in potatoes and in extracts from potatoes

Nutritional Drink Composition

Constituent	Grams	%
Whey Protein	13.00	71.5
Non-Dairy Creamer containing 50% oleic acid	4.00	22.0
Calcium Lactate	0.635	3.5
Flavor	0.19	1.0
Color	0.05	0.3
POT 2 ¹	0.30	1.7

¹ POT 2 includes approx. 10% by weight of the proteinase inhibitor

Hunger ratings following ingestion of the nutritional drink composition were
 5 significantly decreased throughout the post-meal measurement period, reaching a 30% decrease
 by 3 hours post meal ($p=0.033$). Consistent with this finding, fullness ratings were significantly
 greater starting 3 hours post meal (37% increase, $p=0.043$). No differences in subjective ratings
 of other hunger-related items, or in thirst, were observed between the conditions.

Accordingly, an advantage of the present invention is that it provides for a nutritional
 10 intervention composition for extending satiety and reducing hunger following the termination of
 a meal.

Experiment 2:

This study was conducted with 21 subjects having a mean BMI = 31.2 kg/m^2 (range 27.0
 15 – 35.8) and mean age = 30.9 years (range 22 – 45). During the diet, subjects drank 8 oz. (80
 kcal) of the nutritional drink composition of Experiment 1 twice daily fifteen minutes before
 lunch and dinner. The effect of the nutritional drink composition on satiety was measured in a
 laboratory before and in the fourth week of the diet. On separate days subjects ingested the
 nutritional drink composition beverage or a placebo beverage (matched for volume and energy)
 20 fifteen minutes before a 350 calorie meal. Subjects rated hunger and fullness on visual analog
 scales every 15 minutes for 3 ½ hours.

What is claimed is:

1. A nutritional composition in a dry powder form that is mixed with water and ingested
5 before a meal which extends satiety and thereby reduces appetite, comprising:
 - (a) a protein comprising between about 10% and about 80% by weight of said dry composition;
 - (b) one or more fatty acids comprising between about 10% and about 40% by weight
of said dry composition;
 - 10 (c) a calcium salt comprising between about 2% and about 5% by weight of said dry composition; and
 - (d) an extract of potatoes providing a source of proteinase inhibitor that comprises between about 0.02% and about 5% by weight of said dry composition.

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FIG. 1

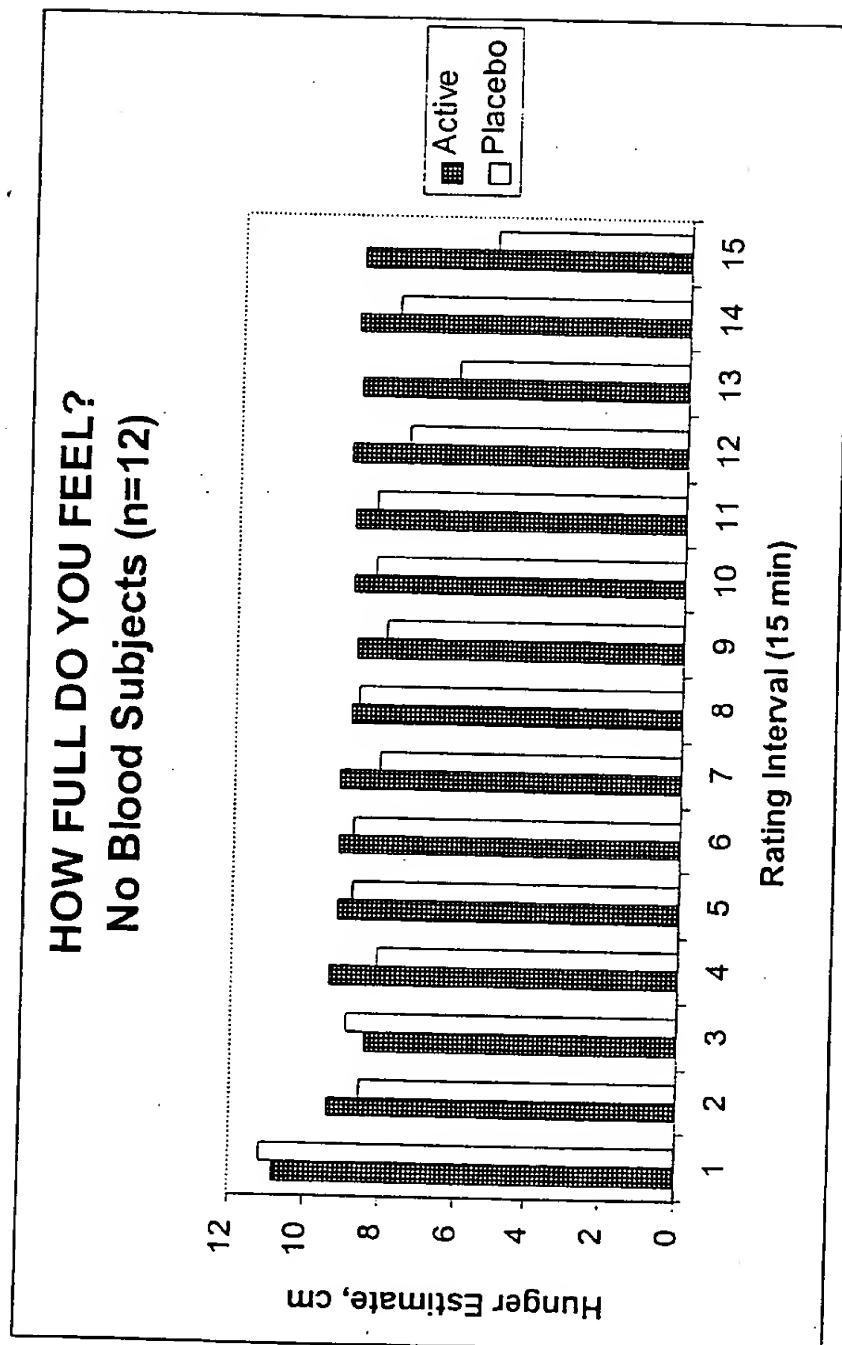
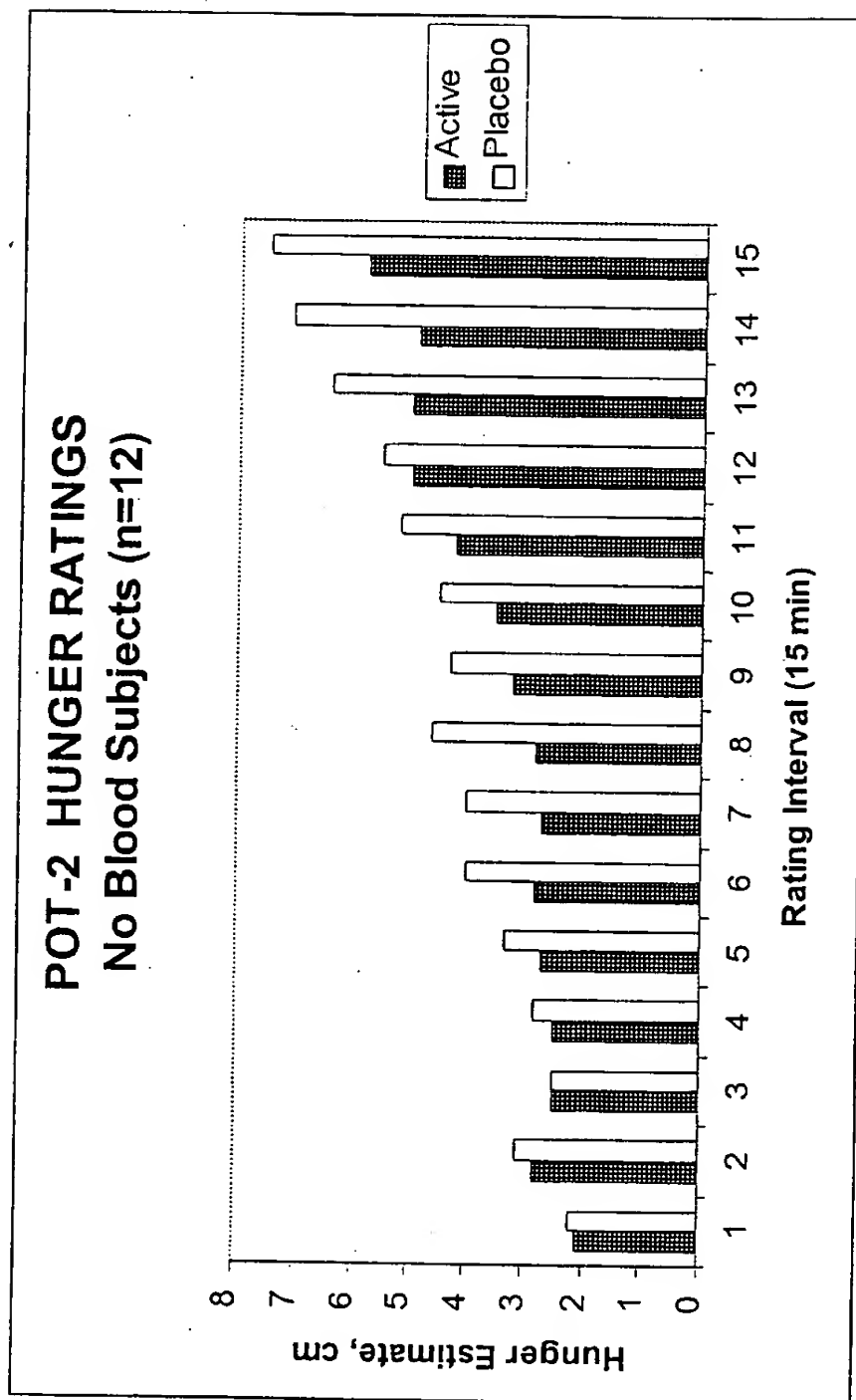


FIG. 2



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/20157**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(7) : A61K 35/78, 33/06, 38/00, 31/20

US CL : 424/195.1, 682; 514/2, 560

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 424/195.1, 682; 514/2, 560

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4,491,578 A (PEIKIN) 01 January 1985 (01.01.1985), see the entire document.	1-5
A	US 5,221,668 A (HENNINGFIELD et al.) 22 June 1993 (22.06.1993), see the entire document	1-5
A	US 5,340,603 A (NEYLAN et al.) 23 August 1994 (23.08.1994), see the entire document.	1-5

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* Later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
E earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*A* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
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